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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/807,221	03/23/2004	Janakraj Karamchand Mehra	IPCA	3311

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EXAMINER

BARTS, SAMUEL A

ART UNIT	PAPER NUMBER
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1621

DATE MAILED: 10/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/807,221	Applicant(s) MEHRA ET AL.	
	Examiner Samuel A. Barts	Art Unit 1621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 July 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) 8-14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed 7/5/2006 have been fully considered but they are not persuasive.

Response to Arguments Pertaining to Anticipation Rejections.

Applicant's arguments with respect to the rejection of Baro et al are convincing.

In essence, Baro et al failed to teach the same order of addition of the reactants. This difference is sufficient to remove Baro et al as anticipatory prior art. However, the examiner would note that this difference is obvious and well within the skill of an ordinary artisan. Even applicants own description of Baro et al in their specification does not highlight the order of addition of the reactants. Applicants state the following in describing Baro et al:

*...5,082,969.... Describes a process for manufacturing metoprolol, where 4-(2-methoxyethyl) phenol and epichlorohydrin are reacted in aqueous alkaline condition at 0°-25° C...*¹

This is substantially the description used to describe step B of instant claim 1.

Applicant's arguments with respect to the rejection of Palmer et al are not convincing.

Applicant states that the office action failed to correctly allege that Palmer's Working Example teaches elements C), D), E), F) and I)². This argument is found not convincing because the examiner has made an anticipation rejection over the reference of Palmer pointing to the Working Example as evidence. Applicant does not deny that column 3 lines 6-49 in Palmer et al anticipate the claim but rather argues that the examiner has not to their satisfaction demonstrated where each step exists in this example. The step by step comparison of the prior art to the claim requested by applicant is not an absolute requirement in establishing an anticipation rejection. As stated in applicant's own rebuttal, anticipation exists where

¹ See page 2 lines 2-4 or applicant's specification.

² Please note that there is no Step I) in instant claim 1.

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each and every element set forth in the claim is found, either expressly or inherently in a single prior art reference. All the elements of claim 1 are in column 3 lines 6-49 in Palmer et al.

The rejection is being maintained.

Response to Arguments Pertaining to the Obviousness Rejection.

Applicant emphasizes again that the claimed elements are not disclosed in the prior art. This is not found convincing for reasons already stated.

Furthermore applicants own summary of their invention over the prior art is as follows:

“The present invention involves optimization of reaction temperatures, molar ratio of reactants in order to achieve higher purity and yields by avoiding purification of epoxide intermediates.

The general process involves three steps :

Step - 1 : reacting 2-(methoxyethyl) phenol with epichlorohydrin organic phase is washed thrice by water with pH in the range of 7 to 8.

Step - 2 : reacting epoxide with isopropyl amine to form Metoprolol base.

Step - 3 : reacting metoprolol base to form a Metoprolol salt.”

Thus applicant's describes his own invention over these two references as an optimization process. The three steps which summarized the claims are taught in the prior art.

Applicant's arguments with respect to pH are not convincing. The pH of water used in the prior would be expected to be around 7 because it is a scientific fact that pure water has a pH of 7. Applicant's claims read on a pH of 7.

Applicant addresses pH like it was not present in the prior art. For example applicant states on page 10 of response that:

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“In the instant case, the OFFICE ACTION fails to allege that the prior art teaches any particular pH of the reaction mixture at all, much less teach that pH is a result effective variable. Thus the art of record fails to suggest modifying that variable in the claimed manner.”

This argument is not convincing for numerous reasons.

An obvious rejection is not over what is explicitly disclosed in the art alone. It takes into account all the knowledge that one of ordinary skill in the art would have possessed at the time of applicant's invention. Every chemist knows that water has a pH around 7. Thus applicant's claims which include the pH of 7 read on the inherent use of water in the prior art whether it was recognized as an important variable of optimization or not.

Response to Arguments Pertaining Mehra's Declaration.

The declaration was considered and found not convincing. It appears to mostly compare the inventions of Baro and Palmer to the invention of this application. However, the instant claims do not reflect the alleged parameters that indicate an advantage over the prior art. For example, the declaration states “On the contrary, the instant invention clearly claims carrying out the reaction at 42.5 ± 2.5 °C. This is not a convincing argument because the temperature 42.5 ± 2.5 °C. is not recited in claim 1.

The declaration alleges that the advantages of the claimed invention were not recognized in the prior art. This may or may not be true however, the instant claims do not highlight these advantages. For example, Mehra interprets claim 1 as teaching a range of pH. This is not the correct construction of the claim. Claim 1 reads on a process using water that has any pH that falls within that range. Since, the range reads on neutral water it is reasonable to assume that the water used in the prior art was within the claimed range.

The alleged synergistic results have not been clearly demonstrated. Applicant would be advised that such a declaration should show that applicant has not only optimized the invention but found some

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critical range of parameters that are not disclosed in the prior art. Also, applicant would be advised that the comparison to prior art should be commensurate in scope with the claimed language.

Claim Rejections - 35 USC § 102

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim 1 rejected under 35 U.S.C. 102(b) as being anticipated by Palmer et al.

For reasons see above responses and previous office action.

Claim Rejections - 35 USC § 103

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baro et al and Palmer et al. For reasons see above responses and previous office action.

Conclusion

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

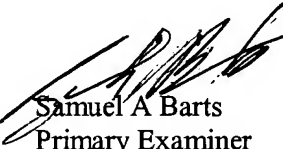
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel A. Barts whose telephone number is 571-272-2870. The examiner can normally be reached on 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Samuel A Barts
Primary Examiner
Art Unit 1621

SB